transfer container is not integrally attached to the blood container, and the blood container is entered after blood collection, the plasma shall be separated from the red blood cells with positive pressure maintained on the original container until completely sealed. If the method of separation involves a vented system, that is, when an airway must be inserted in the container for withdrawal of the plasma, the airway and vent shall be sterile and constructed so as to exclude microorganisms and maintain a sterile system.

(c) *Final containers.* Final containers used for Red Blood Cells shall be the original blood containers unless the method of processing requires a different container. The final container shall meet the requirements for blood containers prescribed in §640.2(c). At the time of filing, if a different container is used, it shall be marked or identified by number or other symbol so as to relate it to the donor of that unit of red cells.

[38 FR 32089, Nov. 20, 1973, as amended at 43 FR 34460, Aug. 4, 1978; 50 FR 4139, Jan. 29, 1985]

§640.17 Modifications for specific products.

Red Blood Cells Frozen: A cryophylactic substance may be added to the Red Blood Cells for extended manufacturers' storage at −65° C. or colder, provided the manufacturer submits data considered by the Director, Center for Biologics Evaluation and Research, as adequately demonstrating through in vivo cell survival and other appropriate tests that the addition of the substance, the materials used and the processing methods results in a final product that meets the required standards of safety, purity, and potency for Red Blood Cells, and that the frozen product will maintain those properties for the prescribed dating period. Section 640.11 (a) and (b) do not apply while a cryophylactic substance is present.

[38 FR 32089, Nov. 20, 1973, as amended at 41 FR 18292, May 3, 1976; 49 FR 23834, June 8, 1984; 50 FR 4139, Jan. 29, 1985; 55 FR 11013, Mar. 26, 1990]

Subpart C—Platelets

§640.20 Platelets.

(a) *Proper name and definition.* The proper name of this product shall be Platelets. The product is defined as platelets collected from one unit of blood and resuspended in an appropriate volume of original plasma, as prescribed in §640.24(d).

(b) *Source.* The source material for Platelets shall be plasma which may be obtained by whole blood collection, by plasmapheresis, or by plateletpheresis.

[40 FR 4304, Jan. 29, 1975, as amended at 47 FR 49021, Oct. 29, 1982; 50 FR 4139, Jan. 29, 1985]

§640.21 Suitability of donors.

(a) Whole blood donors shall meet the criteria for suitability prescribed in §640.3.

(b) Plasmapheresis donors shall meet the criteria for suitability prescribed in §640.63, excluding the phrase ''other than malaria'' in paragraph (c)(9). Informed consent shall be required as prescribed in §640.61.

(c) Plateletpheresis donors shall meet criteria for suitability as described in a license application or a supplement to the product license, and must have the written approval of the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

[40 FR 4304, Jan. 29, 1975, as amended at 49 FR 23834, June 8, 1984; 55 FR 11013, Mar. 26, 1990; 59 FR 49351, Sept. 28, 1994]

§640.22 Collection of source material.

(a) Whole blood used as the source of Platelets shall be collected as prescribed in §640.4, except that paragraphs (d)(2) and (h) shall not apply.

(b) If plasmapheresis is used, the procedure for collection shall be prescribed in §§640.62, 640.64 (except paragraph (c)(3)), and 640.65.

(c) If plateletpheresis is used, the procedure for collection shall be as described in a license application or a supplement to a product license, and must have the written approval of the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.